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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/074,472    05/07/98    RICHTER

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EXAMINER

HM22/0118

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ART UNIT

PAPER NUMBER

1655

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/074,472

Applicant(s)

Richter et al

Examiner

Arun Chakrabarti

Group Art Unit

1655



☒ Responsive to communication(s) filed on Dec 19, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-23 and 25-27 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-23 and 25-27 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 19

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on December 19, 2000, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09074472 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 25 are rejected over the recitation of the negative limitations “wherein said ECL label and said analyte are not identical” and “wherein said ECL quenching moiety and said ECL label are not identical” in claims 1 and 25 respectively (See MPEP 2173.05 (I)) -- “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed. Cir. 1984). The

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mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement". In the instant application, negative limitations inserted in the amended claims do not have any expressed basis in the original specification (as described in Examples 1-14, pages 49-67).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6, 9, 19-21 and 24-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Aizawa et al. (Proceedings of Electrochemical Society (1993), Vol. 93-7, pages 662-73) in view of Tyagi et al. (U.S. Patent 5,925,517) (July 20, 1999)

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Aizawa et al. teaches a method for detecting an analyte in a sample composition (abstract) comprising the steps of:

(a) preparing an assay mixture comprising: said sample composition; a reagent having an ECL label (Abstract);

(b) determining any difference between the ECL emissions of: (I) the assay mixture prepared in step (a); and, (ii) an assay mixture comprising: said reagent having an ECL label; and a known amount of said analyte; and, c) correlating any difference determined in step (b) with the amount of analyte in said sample (Electrochemiluminescence Immunosensing Section and Figures 2 and 6).

Aizawa et al. teaches a method wherein said ECL label comprises a polyaromatic hydrocarbon (Figure 7).

Aizawa et al. teaches a method wherein said ECL label comprises Ruthenium or Osmium (Figure 7).

Aizawa et al. teach the method wherein said analyte comprises an oligonucleotide (DNA or RNA), polypeptide, antibody, antigen, an enzyme, an enzyme substrate, polysaccharide.

Aizawa et al. teaches a method wherein known amount of analyte is zero (Figures 6 and 11).

Aizawa et al do not teach a method wherein reagent having an ECL quenching moiety, said ECL quenching moiety comprising at least one benzene moiety (Materials and Methods Section and Table 1); said ECL quenching moiety comprises at least one moiety selected from

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the group consisting of phenol moieties, quinone moieties, benzene carboxylic acid moieties, and benzene carboxylate moieties.

Aizawa et al do not teach a method wherein said reagent having an ECL label and said reagent having an ECL quenching moiety are either same or different reagent.

Tyagi et al. teach the method wherein the quenching moiety comprises at least one phenol moiety, at least one benzene carboxylic acid moiety or at least one benzene carboxylate moieties (Abstract and column 16, lines 41 to column 17, line 3 and Figure 3). Fluorescein, the quenching label, has at least two benzene moieties.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include the group of chemicals containing substituted benzene rings of Tyagi et al. in the method of Aizawa et al., since Tyagi et al. states "By using multiple probes with interactive labels that generate different, non-interfering detectable signals, e.g., fluorescence at different wavelengths or fluorescence and colored product formation, assays of this invention can detect multiple targets in a single assay (Column 21, lines 24-28)." An ordinary practitioner would have been motivated to combine and compare the electrochemiluminescence quenching chemicals containing differentially substituted benzene ring of Tyagi et al. into the method of Aizawa et al. in order to achieve the express advantages noted by Tyagi et al. of electrochemiluminescence quenching chemicals which provide detection of multiple targets in a single assay.

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6. Claims 1, 2, 4, 9, 19-21 and 24-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Aizawa et al. (Proceedings of Electrochemical Society (1993), Vol. 93-7, pages 662-73) in view of Tyagi et al. (U.S. Patent 5,925,517) (July 20, 1999) further in view of Stratagene Catalog (1988, Page 39).

Aizawa et al in view of Tyagi et al. expressly teach the method claims and assay reagents of 1, 2, 4, 9, 19-21, 24 and 25 as described above in detail.

Aizawa et al in view of Tyagi et al. does not teach the motivation to combine all the reagents for detecting an analyte in a sample in the form of a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine a suitable container, ECL label and ECL quenching moiety of Chmura et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves

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money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control". (page 39, column 1).

***Conclusion***

7. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)




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306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Arun Chakrabarti,

Patent Examiner,

January 13, 2001

  
JEFFREY FREDMAN  
PRIMARY EXAMINER